ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
Semintra 10 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Telmisartan 4 mg or 10 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride	0.1 mg
Hydroxyethylcellulose	-
Sodium hydroxide (for pH adjustment)	-
Hydrochloric acid (for pH adjustment)	-
Maltitol	-
Purified water	-

Clear, colourless to yellowish viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Reduction of proteinuria associated with chronic kidney disease (CKD) in cats.
Treatment of systemic hypertension in cats.

3.3 Contraindications

Do not use during pregnancy or lactation (see also section 3.7).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

The safety and efficacy of telmisartan for the management of systemic hypertension above 200 mmHg has not been investigated.

3.5 Special precautions for use

Special precautions for safe use in the target species:
The safety and efficacy of telmisartan has not been tested in cats under the age of 6 months.
It is good clinical practice to monitor the blood pressure of cats receiving the veterinary medicinal product which are under anaesthesia.
Due to the mode of action of the veterinary medicinal product, transient hypotension may occur. Symptomatic treatment, e.g. fluid therapy, should be provided in case of any clinical signs of hypotension. The dosage of telmisartan should be reduced if systolic blood pressure (SBP) is consistently lower than 120 mmHg or if there are concurrent signs of hypotension.

As known from substances acting on the Renin-Angiotensin-Aldosterone System (RAAS), a slight decrease in red blood cell count may occur. Red blood cell count should be monitored during therapy.

Substances acting on the RAAS may lead to a reduction in glomerular filtration rate and worsening renal function in cats with severe kidney disease. The safety and efficacy of telmisartan in such patients has not been investigated. When using this product in cats with severe kidney disease, it is advisable to monitor renal function (plasma creatinine concentration).

In cats with hypertension it is good clinical practice to regularly monitor blood pressure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid eye contact. In case of accidental eye contact, rinse eyes with water.
Wash hands after use.
Pregnant women should take special care to avoid contact with the product because substances acting on the RAAS, such as Angiotensin Receptor Blockers (ARBs) and ACE inhibitors (ACEis), have been found to affect the unborn child during pregnancy in humans.

People with hypersensitivity to telmisartan or other sartans/ARBs should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Gastrointestinal signs (regurgitation[1], vomiting[2] diarrhoea[2]). Elevated renal parameters (creatinine and/or blood urea nitrogen), chronic renal failure.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated liver enzymes[3]. Decreased red blood cell counts (see section 3.5).

[1] Mild and intermittent
[2] Vomiting and diarrhoea are commonly reported when given at the initial treatment dose of 2 mg/kg for systemic hypertension. Mild and transient
[3] Values normalised within a few days following cessation of therapy.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing

authorisation holder or its local representative or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating cats.
Do not use during pregnancy and lactation (see section 3.3).

3.8 Interaction with other medicinal products and other forms of interaction

No drug-drug interactions are known from available data in cats with CKD and/or hypertension for the use of telmisartan and other medicinal products that lower blood pressure (such as amlodipine) or interfere with RAAS (such as ARBs or ACEis). The combination of such agents may lead to additive hypotensive effects or may alter renal function.

During concomitant therapy with amlodipine at the recommended dose for the reduction of proteinuria associated with chronic kidney disease (CKD) in cats, no clinical evidence of hypotension was observed.

3.9 Administration routes and dosage

Oral use.

The product is to be administered once daily directly into the mouth or with a small amount of food. The veterinary medicinal product is an oral solution and is well accepted by most cats.

The solution should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a ml scale.

After administration of the veterinary medicinal product, close the bottle tightly with the cap, wash the measuring syringe with water and let it dry.

To avoid contamination, use the provided syringe only to administer the veterinary medicinal product.

CKD – amounts to be administered once daily:
The recommended dose is 1 mg telmisartan/kg body weight.

Dosing: 1 mg telmisartan/kg body weight	
Strength [mg/ml]	Dosage/kg bodyweight [ml]
4	0.25
10	0.1

Systemic hypertension – amounts to be administered once daily:
The initial recommended dose is 2 mg telmisartan/kg body weight.

Dosing: 2 mg telmisartan/kg body weight	
Strength [mg/ml]	Dosage/kg bodyweight [ml]
4	0.5
10	0.2

After 4 weeks, the dosage of telmisartan may be reduced in cats with systolic blood pressure (SBP) of less than 140 mmHg (in 0.5 mg/kg increments) at the discretion of the veterinarian.
If the SBP increases over the course of the disease the daily dose may be increased again up to 2 mg/kg.
The target SBP range is between 120 and 140 mmHg. If SBP is below the target or if there are concurrent signs of hypotension, please refer to section 3.5.

Systemic hypertension associated with CKD – amounts to be administered once daily:
The dosing regimen for hypertensive cats with concomitant chronic kidney disease is as described above for systemic hypertension except that for these cats the recommended minimum effective dose is 1 mg/kg.

3.10 Symptoms of overdose (and where applicable emergency procedures, antidotes)

After administration of up to 5 mg/kg body weight for 6 months to young adult healthy cats, adverse reactions observed were consistent with those mentioned in section 3.6.

Administration of the product at overdose (up to 5 mg/kg body weight for 6 months) resulted in marked reductions in blood pressure, decreases in red blood cell count (effects attributable to the pharmacological activity of the product) and increases in Blood Urea Nitrogen (BUN).

In the event that hypotension does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QC09CA07

4.2 Pharmacodynamics

Telmisartan is an orally active and specific angiotensin II receptor (subtype AT_1) antagonist which causes a dose-dependent decrease in mean arterial blood pressure in mammalian species, including the cat. In a clinical trial in cats with chronic kidney disease, a reduction in proteinuria was seen within the first 7 days after the start of treatment with 1 mg/kg. In a further clinical trial in cats with hypertension a reduction in mean systolic blood pressure was achieved with a dose of 2 mg/kg. Due to the combination of these pharmacodynamic properties, telmisartan is an appropriate treatment for cats with concomitant hypertension and CKD.

Telmisartan displaces angiotensin II from its binding site at the AT_1 receptor subtype. Telmisartan selectively binds to the AT_1 receptor and does not show affinity for other receptors, including AT_2 or other less characterised AT receptors. Stimulation of the AT_1 receptor is responsible for pathologic effects of angiotensin II in the kidney and other organs associated with angiotensin II such as vasoconstriction, retention of sodium and water, increased aldosterone synthesis and organ remodelling. Effects associated with stimulation of the AT_2 receptor such as vasodilatation, natriuresis and inhibition of inappropriate cell growth are not suppressed. The receptor binding is long lasting due to the slow dissociation of telmisartan from the AT_1 receptor binding site. Telmisartan does not exhibit any partial agonist activity at the AT_1 receptor.

Hypokalaemia is associated with CKD, however telmisartan does not affect potassium excretion, as shown in the clinical field trial in cats.

4.3 Pharmacokinetics

Absorption
Following oral administration of telmisartan to cats, plasma-concentration-time curves of the parent compound are characterised by rapid absorption, with maximum plasma concentrations (C_{max}) achieved after 0.5 hours (t_{max}). For both, C_{max}-values, and AUC-values, a dose proportional increase over the dose range from 0.5 mg/kg to 3 mg/kg was observed. As determined by AUC, food consumption does not affect the overall extent of absorption of telmisartan.

Telmisartan is highly lipophilic and has rapid membrane permeability kinetics, which facilitates easy distribution into tissue. No significant gender effect was seen.

No clinically relevant accumulation was observed following multiple dose administration once daily for 21 days. The absolute bioavailability after oral administration was found to be 33%.

Distribution
In vitro studies in human, dog, mouse and rat plasma showed a high plasma protein binding (>99.5%), mainly to albumin and α-1-acid glycoprotein.

Metabolism
Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate. From *in vitro* and *ex vivo* studies with feline liver microsomes it can be concluded that telmisartan is effectively glucuronidated in the cat. The glucuronidation resulted in the formation of the 1-*O*-acylglucuronide metabolite of telmisartan.

Elimination
The terminal elimination half-life ($t_{1/2}$) ranged from 7.3 hours to 8.6 hours, with mean value 7.7 hours. After oral administration, telmisartan is almost exclusively excreted in the faeces mainly as the unchanged active substance.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
Semintra 4 mg/ml oral solution for cats (30 ml or 100 ml): 3 years.
Semintra 10 mg/ml oral solution for cats (35 ml): 2 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

One HDPE bottle filled with:
4 mg/ml: 30 ml or 100 ml
10 mg/ml: 35 ml

Each bottle is closed with an LDPE plug-in adapter and a tamper-proof child resistant closure.
Pack size: one bottle of 30 ml, 35 ml or 100 ml and one measuring syringe in a cardboard box.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/146/001 - 003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 13.02.2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
Detailed information on this veterinary medicinal product is available in the Union Product Database.

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 30 ml and 100 ml (4 mg/ml) and 35 ml (10 mg/ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
Semintra 10 mg/ml oral solution for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 4 mg/ml
Telmisartan 10 mg/ml

3. PACKAGE SIZE

30 ml
35 ml
100 ml
1 measuring syringe

4. TARGET SPECIES

Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp {mm/yyyy}
Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

14. MARKETING AUTHORISATION NUMBERS

EU/2/12/146/001 (30 ml (4 mg/ml))
EU/2/12/146/002 (100 ml (4 mg/ml))
EU/2/12/146/003 (35 ml (10 mg/ml))

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle of 100 ml (4 mg/ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 4 mg/ml

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp {mm/yyyy}
Once opened use by ....

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle of 30 ml (4 mg/ml) and 35 ml (10 mg/ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Telmisartan 4 mg/ml
Telmisartan 10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once opened use by ....

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Semintra 4 mg/ml oral solution for cats
Semintra 10 mg/ml oral solution for cats

2. Composition

Each ml contains:
Telmisartan 4 mg or 10 mg

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride	0.1 mg

Clear, colourless to yellowish viscous solution.

3. Target species

Cats.

4. Indications for use

Reduction of proteinuria associated with chronic kidney disease (CKD) in cats.
Treatment of systemic hypertension in cats.

5. Contraindications

Do not use during pregnancy or lactation. See section "Pregnancy and lactation".
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

The safety and efficacy of telmisartan for the management of systemic hypertension above 200 mmHg has not been investigated.

Special precautions for safe use in target species:
The safety and efficacy of telmisartan has not been tested in cats under the age of 6 months.
It is good clinical practice to monitor the blood pressure of cats receiving the veterinary medicinal product which are under anaesthesia.

Due to the mode of action of the veterinary medicinal product, transient hypotension (low blood pressure) may occur. Symptomatic treatment, e.g. fluid therapy, should be provided in case of any clinical signs of hypotension. The dosage of telmisartan should be reduced if systolic blood pressure (SBP) is consistently lower than 120 mmHg or if there are concurrent signs of hypotension.

As known from substances acting on the Renin-Angiotensin-Aldosterone System (RAAS), a slight decrease in red blood cell count may occur. Red blood cell count should be monitored during therapy.

Substances acting on the RAAS may lead to a reduction in glomerular filtration rate and worsening renal function in cats with severe kidney disease. The safety and efficacy of telmisartan in such patients has not been investigated. When using this product in cats with severe kidney disease, it is advisable to monitor renal function (plasma creatinine concentration).

In cats with hypertension it is good clinical practice to regularly monitor blood pressure.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid eye contact. In case of accidental eye contact, rinse eyes with water.
Wash hands after use.
Pregnant women should take special care to avoid contact with the product because substances acting on the RAAS, such as Angiotensin Receptor Blockers (ARBs) and ACE inhibitors (ACEis), have been found to affect the unborn child during pregnancy in humans.

People with hypersensitivity to telmisartan or other sartans/ARBs should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating cats.
Do not use during pregnancy and lactation. See section “Contraindications”.

Interaction with other medicinal products and other forms of interaction:
No drug-drug interactions are known from available data in cats with CKD and/or hypertension for the use of telmisartan and other medicinal products that lower blood pressure (such as amlodipine) or interfere with RAAS (such as ARBs or ACEis). The combination of such agents may lead to additive hypotensive effects or may alter renal function.

During concomitant therapy with amlodipine at the recommended dose for the reduction of proteinuria associated with chronic kidney disease (CKD) in cats, no clinical evidence of hypotension was observed.

Overdose:
After administration of up to 5 mg/kg body weightfor 6 months to young adult healthy cats, adverse reactions observed were consistent with those mentioned in section “Adverse events”.

Administration of the product at overdose (up to 5 mg/kg body weight for 6 months) resulted in marked reductions in blood pressure, decreases in red blood cell count (effects attributable to the pharmacological activity of the product) and increases in Blood Urea Nitrogen (BUN; nitrogen containing waste products in the blood).

In the event that hypotension does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

Major Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary products.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):
Gastrointestinal signs (regurgitation[1], vomiting[2] diarrhoea[2]). Elevated renal parameters (creatinine and/or blood urea nitrogen), chronic renal failure.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Elevated liver enzymes[3]. Decreased red blood cell counts (see section "Special warnings").

[1] Mild and intermittent
[2]Vomiting and diarrhoea are commonly reported when given at the initial treatment dose of 2 mg/kg for systemic hypertension. Mild and transient
[3] Values normalised within a few days following cessation of therapy.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Oral use.

The product is to be administered once daily directly into the mouth or with a small amount of food. The veterinary medicinal product is an oral solution and is well accepted by most cats.

The solution should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a ml scale.

CKD – amounts to be administered once daily:
The recommended dose is 1 mg telmisartan/kg body weight.

Dosing: 1 mg telmisartan/kg body weight	
Strength [mg/ml]	Dosage/kg bodyweight [ml]
4	0.25
10	0.1

Systemic hypertension – amounts to be administered once daily:
The initial recommended dose is 2 mg telmisartan/kg body weight.

Dosing: 2 mg telmisartan/kg body weight	
Strength [mg/ml]	Dosage/kg bodyweight [ml]
4	0.5
10	0.2

After 4 weeks, the dosage of telmisartan may be reduced in cats with systolic blood pressure (SBP) of less than 140 mmHg (in 0.5 mg/kg increments) at the discretion of the veterinarian.
If the SBP increases over the course of the disease the daily dose may be increased again up to 2 mg/kg.
The target SBP range is between 120 and 140 mmHg. If SBP is below the target or if there are concurrent signs of hypotension, please refer to section 'Special warnings'.

Systemic hypertension associated with CKD – amounts to be administered once daily:
The dosing regimen for hypertensive cats with concomitant chronic kidney disease is as described above for systemic hypertension except that for these cats the recommended minimum effective dose is 1 mg/kg.

9. Advice on correct administration

Push down and turn cap to open the bottle. Attach the dosing syringe to the plug-in adapter of the bottle by gently pushing.
Turn the bottle/syringe upside down. Pull the plunger out until the end of the plunger corresponds to the amount needed in ml.Separate the dosing syringe from the bottle.

Push the plunger to empty the contents of the syringe directly into the mouth of the cat …

… or onto a small amount of food.

After administration of the veterinary medicinal product close the bottle tightly with the cap,…

… wash the measuring syringe with water and let it dry.

To avoid contamination, use the provided syringe only to administer the veterinary medicinal product.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/12/146/001 - 003

Pack size: one plastic bottle filled with 30 ml or 100 ml (4 mg/ml) or one plastic bottle filled with 35 ml (10 mg/ml).
1 measuring syringe.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
Tél/Tel: + 32 2 773 34 56

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